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K002683

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the WMT **ULTRA-FIT™** Modular Shoulder System.

Submitted By:	**Wright Medical Technology, Inc.**
Date:	August 24, 2000
Contact Person:	**Ehab M. Esmail** Senior Regulatory Affairs Associate
Proprietary Name:	WMT **ULTRA-FIT™** Modular Shoulder System
Common Name:	Modular Shoulder System
Classification Name and Reference:	21 CFR 888.3660 Prosthesis, Shoulder, Semi-Constrained, metal/polymer, Cemented – Class II 21 CFR 888.3690 Prosthesis, Shoulder, Hemi-, Humeral, Metallic, Uncemented – Class II
Device Product Code and Panel Code:	Orthopedics/87/KWS, HSD

DEVICE INFORMATION

A. INTENDED USE

The indications for use for the WMT ULTRA-FIT™ Modular Shoulder System will be substantially equivalent to the indication for use listed under the following submissions. (Table 1 – Total Shoulder Systems Cleared for Market)

The WMT Modular Shoulder is indicated for use in shoulder arthroplasty for reduction or relief of pain and/or improved shoulder function in skeletally mature patients with sufficient and satisfactory bone stock to support the prosthesis with the following conditions:

Indications for Use:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis or post-traumatic arthritis;
- Revision where other devices or treatments have failed;
- Correction of functional deformity;
- Treatment of acute fracture of the humeral head unmanageable using other treatment methods; and
- Cuff tear arthroplasty.

Hemi-shoulder replacement is also indicated for:

- Ununited humeral head fractures; and
- Avascular necrosis of the humeral head.

The humeral stem may be implanted by press-fit or cement fixation.

Table 1 - Total Shoulder Systems Cleared for Market Cleared for Market

Description	Submission Number	Clearance Date
WMT -Modular Shoulder System	K001706	08/16/2000
3M™ -Modular Shoulder System	K920362	07/22/1993
DePuy® -Global Advantage Shoulder, Global Advantage Humer	K992065	07/12/1999
Biomet- BioModular® Shoulder Humeral Head W/Ionguard	K915596	03/11/1992
Zimmer- New Zimmer Shoulder System (Bigliani/Flatow™)	K982981	12/17/1998

The components included in the WMT ULTRA-FIT™ Modular Shoulder System are for single use only.

B. DEVICE DESCRIPTION

The WMT ULTRA-FIT™ Modular Shoulder System consists of three main components: humeral stem, humeral head, and glenoid implants. All heads will be interchangeable with all stems, and glenoids will be matched to humeral heads. The glenoids will be available in two designs: The 3M-like glenoids are identical in intended use, type of interface, material, and design features to the 3M glenoid component submitted under 3M Modular Shoulder System (Table 1: K920362, SE 07/22/1993) currently distributed by WMT; and the WMT ULTRA-FIT™ Glenoids that are described below.

The WMT ULTRA-FIT™ Humeral Stems will be available in four options:

- Press-fit slotted stems (4): 10,12,14,16mm X 125mm
- Cemented or press-fit non-slotted stems (7): 6, 8, 10, 12, 14, 16mm X 125mm; 6mm X110mm
- Standard revision stems (4): 6, 8, 10, 12mm X 175mm
- Long revision stems (4): 6, 8, 10, 12mm X 225mm

The WMT ULTRA-FIT™ Humeral Heads will be available in:

- 5 radii of curvature: 20, 22, 24, 26, and 28mm
- 3 heights: standard (defined by 155° to 160° arc), +3mm, and –3mm

The WMT ULTRA-FIT™ Glenoids will be available in:

- 6 radii of curvature (Keeled)

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of the WMT ULTRA-FIT™ Modular Shoulder System are substantially equivalent to the competitive devices listed in Table 1. The safety and effectiveness of WMT ULTRA-FIT™ Modular Shoulder System are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2000

Mr. Ehab M. Esmail
Senior Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K002683
Trade Name: WMT ULTRA-FIT™ Modular Shoulder System
Regulatory Class: II
Product Code: KWS, HSD
Dated: August 24, 2000
Received: August 28, 2000

Dear Mr. Esmail:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

INDICATIONS STATEMENT

WMT **ULTRA-FIT™** Shoulder System
510(K) Number (if known): K002683

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002683

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

Prescription Use ✓
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)